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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,524	12/19/2000	Y. Tom Tang	PC-0022 CIP	9999

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EXAMINER	
HILL, MYRON G	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/747,524	TANG ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 20* is/are pending in the application.

4a) Of the above claim(s) *7- 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1- 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In view of the Appeal Brief filed on 6 June 2003, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

This office action is in response to the papers filed 6 June 2003 in view of the petition decision mailed 5 November 2003.

Claims 1- 6 are under consideration in this office action.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1- 6 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

This rejection is modified and presented below.

New Rejections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The instant application has provided a description of an isolated DNA encoding a protein. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 1 is what is termed in the art an "orphan protein".

This is a protein whose cDNA has been isolated was isolated because of similarity to other known cDNAs. It is not unlikely that, after further characterization, the claimed polynucleotides or the proteins encoded thereby will be found to have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicants claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct,.1966) in which a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The Court held that:

> "The basic quit pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point- where specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field",

and

"a patent is not a hunting license, it is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to nucleic acids which encode a protein of as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as GRIIP (Growth Related Inflammation and Immune Protein), of nucleic acids encoding such or fragments thereof, the instant invention is incomplete. In the absence of any functional or biological significance of this protein, there is no immediately obvious "patentable" use for it. To employ a nucleic acid of the instant invention (or the protein encoded thereby) in the diagnosis, treatment or prevention of developmental, cell proliferative or immunological disorders would clearly require the use of such as an object of further research, as no such disorders have yet to be identified, and thus would require substantial further investigation, which investigation would constitute part of the inventive process itself. Since the instant specification does not disclose a readily available, "real world" use for the claimed polynucleotide of the protein encoded thereby, the claimed invention is incomplete and does not meet the requirement of 35 U.S.C. 101 as being useful. Because the claimed invention is not supported by a specific and substantial asserted utility, credibility will not be assessed.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:
1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The specification discloses SEQ ID NO: 2, and postulates a protein having SEQ ID NO: 1, encoded by such. No activities or diagnostic uses or other significant attributes are ascribed to either the nucleic acid or the protein; the only disclosed feature of the nucleic acid or protein, other than the raw sequences themselves, is that they are expressed in a human. The state of the prior art is that both sequences are novel. Although the relative level of skill in the art is high, the claims are broad, and there are no working examples or guidance or direction to allow the person of ordinary skill in the art to make and use species in a manner commensurate in scope with the claims. With particular respect to claims to nucleic acid which "encodes" protein, if the

nucleic acid were found to have utility as a hybridization probe, such would not be commensurate in scope with such claims, as the majority of such species would not be useful as hybridization probes. It is not recognized practice in the art to alter nucleic acid sequences from their naturally occurring sequences for use as hybridization probes in any method disclosed in the specification, e.g. microarrays. Accordingly, it would require undue experimentation to determine how to use a commensurate number of species.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification sets forth a 1979 residue long polynucleotide of SEQ ID NO: 2, encoding a polypeptide of SEQ ID NO: 1. However, the written description is not commensurate with an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence having at least 90% identity to a sequence of SEQ ID NO: 1.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any

combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a partial structure in the form of a recitation of percent identity to another protein HW051. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a polypeptide comprising SEQ ID NO: 1 or a polynucleotide comprising SEQ ID NO: 2. No active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

The specification provides general principles for making the polynucleotide variants of the claimed sequences encoding the GRIIP polypeptides. However, the disclosure fails to provide a detailed description directed to the intended variants of the polypeptide of SEQ ID NO: 1 including critical features of such that should be conserved. It is not sufficient to name the claimed variant nucleic acids that can encode for polypeptides comprising 90% identity to SEQ ID NO: 1 or the complement of the nucleic acid of SEQ ID NO: 2, or the variant polypeptides without disclosure of what features define the claimed genus. The disclosure fails to describe the common attributes or characteristics that identify the members of the genus. The claimed genus is highly variant, and the disclosure of a specific polypeptide sequence is insufficient to describe the genus consisting of variants of SEQ ID NO: 2, and complementary sequences thereof. One of skill in the art would reasonably conclude that the disclosure

fails to provide a representative number of species or a description of the structural/functional features sufficient to describe the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polynucleotide comprising the sequence set forth in SEQ ID NO: 2, or encoding the protein of SEQ ID NO: 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. 112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

The claims are drawn to "naturally occurring variants" with at least 90% identity to SEQ ID# 1.

Applicant pointed to page 3 and 8.

The examiner does not see support for "naturally occurring variants" or "90%".

Applicant is requested to point out support for the claimed amendments.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
February 5, 2007

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